

VITROS® Immunodiagnostic Products NT-proBNP II Assay

Confidence in Results. Confidence in Decisions.

NT-proBNP is superior to BNP¹

- BNP is impacted by a common heart failure therapy (Entresto®), making it difficult to manage patients on this therapy²
- NT-proBNP is more stable than BNP, which is important when samples must be transported³
- Most NT-proBNP assays correlate well. Not all BNP assays correlate well with other BNP assays⁴

VITROS NT-proBNP II age dependent (ICON) cut-offs

- Only NT-proBNP assays can be validated with the ICON age-specific cut-offs⁵⁻⁹
- ICON cut-offs optimize diagnosis decisions as they account for age and renal function⁵⁻⁹
- ICON cut-offs provide better specificity in cases of acute dyspnea as a symptom of acute HF or acutely decompensated HF¹⁰

Excellent Clinical Performance



Indications for Use

- Aid in diagnosis of heart failure.
- Risk Stratification of acute coronary syndrome and heart failure.
- Aid in the assessment of increased risk of cardiovascular events & mortality in patients who have stable coronary artery disease.
- Aid in the assessment of heart failure severity in patients diagnosed with heart failure.

NT-proBNP II Assay Clinical Performance (All Subjects male/female)

| Age Group (years) | AUC | NPV, % | PPV, % | Sensitivity, % | Specificity, % |
|-------------------|------|--------|--------|----------------|----------------|
| 22 - < 50 | 0.95 | 96.67 | 79.76 | 97.10 | 77.33 |
| 50 - < 75 | 0.92 | 90.28 | 77.64 | 91.01 | 76.11 |
| < 75 | 0.92 | 91.53 | 78.09 | 92.26 | 76.36 |
| ≥ 75 | 0.93 | 81.13 | 89.05 | 90.34 | 78.90 |
| Overall | 0.93 | 88.86 | 81.88 | 91.53 | 76.94 |

You deliver more than results. You deliver trust.

State of the Art **MicroWell Technology**

- One-step immunometric bridging assay
- Monoclonal antibodies
- Analyte-specific coating architecture designed to eliminate biotin susceptibility
- Excellent correlation to Roche Elecsys® proBNP II Immunoassay and to VITROS NT-proBNP simplifies migration
- Runs on all VITROS Immunodiagnostic and Integrated Systems

Highly Competitive **Analytical/Operational Performance**

Measuring range: 20-30,000 pg/mL (2.36-3,540 pmol/L)

Time to First Result: 15 minutes

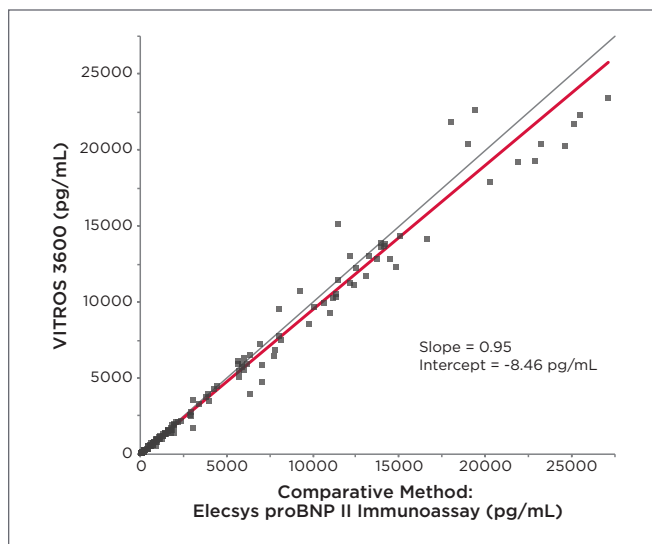
LOD: 0.49 pg/mL

LOQ (20% CV): 20.0 pg/mL (0.56 pg/mL observed)

Sample volume: 40 µL

Sample stability: 2 days at 20–25 °C (68–77 °F), 3 days at 2–8 °C (36–46 °F)

Calibration interval: 70 days



IFU NBNP2 GEM1317_XUS_EN

ACCURACY

Method comparison between Roche Elecsys proBNP II and VITROS NT-proBNP II shows excellent correlation.

Part of the full VITROS line of Quality Cardiac Assays

hs Troponin I, Myoglobin, Apolipoprotein A1, Apolipoprotein B, Cholesterol, CK, CK-MB, Direct HDL, Direct LDL, Homocysteine, Lipoprotein(a)b, Triglycerides

Not all products available in all regions or on all VITROS systems.

ORDERING INFORMATION

| ITEM | CONTENTS | CATALOG NO. |
|--|--------------------------|-------------|
| VITROS NT-proBNP II Reagent Kit | 100 tests/kit | 6844452 |
| VITROS NT-proBNP II Calibrator Liquid, Ready-to-use format | 1 set of 3 levels x 2 mL | 6844453 |
| VITROS NT-proBNP II Controls Liquid frozen format | 1 set of 3 levels x 3 mL | 6844507 |

References

1. Head-to-Head comparison of 10 natriuretic peptide assays. *Clin Chem Lab Med.* 2015; 1-13.
2. Angiotensin Receptor Neprilysin Inhibition Compared with Enalapril on the Risk of Clinical Progression in Surviving Patients with Heart Failure. *Circulation.* 2015;131:54-61.
3. Long-term Stability of Endogenous B-type natriuretic peptide (BNP) and amino terminal proBNP (NT-proBNP) in frozen plasma samples. *Clin Chem Lab Med.* 2004;42(8):942-4.
4. DCollin-Chavagnac et al., Head-to-head comparison of 10 natriuretic peptide Assays. DOI 10.1515/cclm-2014-0592
5. Natriuretic Peptide Testing in Heart Failure. *Circulation.* 2011; 123:2015-2019.
6. Direct comparison of B-type natriuretic peptide (BNP) and amino-terminal proBNP in a large population of patients with chronic and symptomatic heart failure: The Valsartan Heart Failure (Val-HeFT) data. *Clin Chem.* 2006; Aug;52(8):1528-38.
7. The N-terminal Pro-BNP investigation of dyspnea in the emergency department (PRIDE) study. *Am J Cardiol.* 2005 Apr 15;95(8):948-54.
8. NT-proBNP testing for diagnosis and short-term prognosis in acute destabilized heart failure: an international pooled analysis of 1256 patients. *European Heart Journal.* (2006) 27, 330–337.
9. Combined Neprilysin and Renin-Angiotensin System Inhibition for the Treatment of Heart Failure. *JACC: Heart Failure.* 2014; Vol 2, No.6: 663-670.
10. Amino-Terminal Pro-B-Type Natriuretic Peptide Testing and Prognosis in Patients with Acute Dyspnea, Including Those with Acute Heart Failure. *Am J Cardiol.* 2008; 101 [suppl]: 49A-55A.

